DOCKET NO.: NIHB-2203 PATENT

Application No.: 10/667,141

Office Action Dated: December 8, 2009

REMARKS

Upon entry of this communication, claims 67, 73-75, 255, and 278 will be pending. As described herein, claims 67, 255, and 278 are amended to incorporate limitations of claim 76, which is now canceled. No new matter is added in this response.

Rejection under 35 U.S.C. § 112, second paragraph

The Office rejects claim 76 as being indefinite based on Skidapoulos et al. (J. Virol. Vol. 77, 2003), alleging that one of skill in the art would expect that amino acids at particular positions in the HPIV2 L protein may vary. While claim 76 is canceled in this response, Applicants respond to the substance of this rejection, since claims 67, 255, and 278 are amended herein to incorporate limitations previously recited in claim 76.

Applicants disagree with this rejection, as it is in direct contrast to the teaching of Skidapoulos et al. While it is true that Skidapoulos et al. discloses different strains of HPIV2, the point of the article is that these various strains are highly similar – not different, as suggested by the Office. For example, Skidapoulos et al. states quite clearly that the predicted amino acid sequences of the disclosed HPIV2 strains are highly conserved (p. 272, last full paragraph). This relationship is also made clear in Table I of the reference, which shows that of all HPIV2 proteins, the L protein is the most highly conserved – having over 99% identity among the various strains. Similar disclosures are also made in the present application (see, for example, paragraph 222).

Given that the disclosure of Skidapoulos et al. directly contradicts the reasoning underlying the rejection, Applicants submit that the Office has not provided a reasonable basis to challenge the adequacy of the written description by showing, by a preponderance of evidence, why a skilled person would not recognize the invention defined by the claims in the disclosure of the application (MPEP § 2163.04). Therefore, Applicants request that the rejection under § 112 be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claim 76 stands rejected under § 103(a) in view of: Murphy et al. (WO 98/53078); Kawano eta l. (Virology, vol. 284 99-112); Skidapoulos et al. (J. Virol., 1999), and

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Skidapoulos et al. (J. Virol., 1998), with additional consideration of the disclosure of Skidapoulos et al. (J. Virol., 2003). In this regard, the Office seems to have taken the positions that all possible attenuating mutations that could be identified in the more than 2,200 amino acid residues of the HPIV2 L protein are obvious to those skilled in the art, because the prior art discloses 3 attenuating mutations for <u>HIPV3</u> (not HPIV2) and a reverse genetics system to search for such mutations.

Applicants disagree based on the standard for obviousness provided by *In re Kubin*, 90 USPQ2d 1417 (Fed. Cir. 2009). In *Kubin*, the court stated that the obviousness standard was not met where

what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.

Id. at 1423. This rule could hardly be more at odds with the pending rejection. According to the Office, the claimed mutations are obvious because, based on the cited art, one of ordinary skill in the art could individually mutate any of more than 2200 amino acids in order to eventually identify attenuating mutations in the L protein, without any "direction as to which of [the over 2200] possible choices is likely to be successful." *Id.* The present rejection is precisely the sort of misplaced use of § 103 that the courts have continuously guarded against. Thus, the present rejection cannot stand. Therefore, Applicants request the rejection be withdrawn.

Applicants contend that the rejection of claims 67, 73, 74, 75, 255, and 278 as obvious in view of Murphy et al., Kawano et al., and Skidapoulos et al. is inapplicable in view of the claim amendments made herein, which applies limitations of canceled claim 76 to each of the rejected claims. Accordingly, applicants request that the reject be withdrawn.

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Conclusion

Applicants believe the application, with present amendments, is allowable and respectfully request an early issuance of a notice of allowance.

Date: March 8, 2010 /S. Maurice Valla/ S. Maurice Valla

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